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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,715	01/21/2004	Mark E. Cook	960296.00143	3715

27114 7590 08/14/2008
QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE, SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT	PAPER NUMBER
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1644

NOTIFICATION DATE	DELIVERY MODE
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08/14/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

DETAILED ACTION

1. Applicant's response and amendments received May 13, 2008 are acknowledged.

Claims 2-4, 11, 13-24, 26, and 28 have been canceled.

Claims 27 and 40 have been amended.

Claims 1, 5-10, 12, 25, 27, and 29-40 are pending in the instant application.

Claims 1, 5-10, 12, 25, 27, and 29-40 are under examination as they read on methods of administering anti-PLA₂ antibodies that improve body weight uniformity and carcass yield.

The declaration of Mingder Yang under 37 CFR 1.132 which was received May 13, 2008 is acknowledged and will be discussed in conjunction with rejections of record.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5-10, 12, 25, 27 and 30-40 stand rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,213,930 (of record on the 4/29/04 IDS, see entire document) for the reasons of record.

The office action mailed January 24, 2007 states:

The '930 patent teaches methods of administering anti-phospholipase A₂ (anti-PLA₂) antibodies to animals to enhance animal growth and feed efficiency. This patent teaches that PLA₂ cleaves the covalent bond between arachidonic acid and membrane phospholipids, thus releasing arachadonic acid to serve as a prostaglandin/leukotriene precursor (see particularly lines 44-50 of column 1). Note that anti-PLA₂ antibodies are disclosed as inhibiting the activity of PLA₂ which thus effectively limit the bioavailability of

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arachidonic acid (see particularly lines 25-51 of column 2). Animals to be administered anti-PLA₂ antibodies comprise chickens, ducks, turkeys, quail, geese, cows, sheep, pigs, and goats (see particularly lines 8-13 of column 3). The anti-PLA₂ antibodies are administered by a variety of routes, comprising subcutaneously, intraperitoneal, intramuscular, intravenous, and oral, with the oral route being preferred (see particularly lines 52-62 of column 3). The '930 patent further teaches that anti-PLA₂ antibodies can be obtained from the yolk of immunized chickens, and that egg preparations comprising the specific antibody are to be given as a supplement to the animal's diet (see particularly from line 63 of column 3 to line 22 of column 4).

It is noted that the preamble of the instant claims recite "improving body weight uniformity" and "increasing carcass yield" and that these particular phrases are not found within the text of the '930 patent. However, the process steps of the instant claims comprise administering an agent, such as an anti-PLA₂ antibody, to an animal. These process steps are taught by the '930 patent as discussed above. As such it appears that improved body weight uniformity and increased carcass yield are inherent benefits that accrue to an animal upon performance of the methods of administering anti-PLA₂ antibodies disclosed in the '930 patent. Applicant is reminded "[T]he discovery of a previously unappreciated property of a prior art composition (method), or of a scientific explanation for the prior art's functioning, does not render the old composition (method) patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Further, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.").

Given that the same agent is administered to the same patient population, the methods of the '930 patent anticipate the claimed invention.

And the office action mailed July 11, 2007 states:

Applicant's arguments filed April 24, 2007 have been fully considered but they are not persuasive. Applicant argues that the prior art does not anticipate the claimed methods because the prior art does not administer sufficient antibody to observe improved body weight uniformity or carcass yield. Applicant supports this argument with the declaration under 37 CFR 1.132 of coinventor Mingder Yang which purports to show that when chickens are fed the amounts of anti-PLA₂ antibodies disclosed in the working examples of the '930 patent, statistically significant increases in body weight uniformity were not observed.

This argument is not persuasive because applicant is arguing limitations that are not claimed. Specifically, neither the patented claims nor the instant pending claims recite any dosages to be administered. Claims are limited by what they recite, not what is disclosed in the specification.

Further, given that the same agent (anti-PLA₂ antibodies) are administered to the same population (captive-raise chickens) by the same route of administration (mixed into animal feed), any observed phenomena, such as increased growth, decreased gastrointestinal inflammation, enhanced carcass yield, and improved body weight uniformity are inherent since the recited method steps are the same. Note that as part of the administration process, a skilled artisan would need to observe the animals and as such a positive recitation that the animals are observed, such as appears in new claims 27 and 28 is not accorded patentable weight.

And the office action mailed December 19, 2007 states:

Applicant's arguments filed October 10, 2007 have been fully considered but they are not persuasive. Applicant's first argument is that while independent claim 1 and claims dependent therefrom do not recite a dosage, the greatest dosage recited in the prior art was 0.5g/kg and the declaration of Minder Yang previous submitted indicates that such a dosage is insufficient to improve body weight uniformity.

This argument is not persuasive based upon the data presented in Table 1 on page 7 of the instant specification. Table 1 discloses numerous trials wherein various dosages of anti-PLA₂ antibodies were administered and coefficients of variation (CV) of body weight were measured. Note that the specification

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teaches that a reduction in the CV of mean body weight is evidence of improved body weight uniformity. Note that antibodies at 0.5g/kg were administered in trials 2-5 and in all of these trials the 0.5g/kg dosage decreased the measured CV as compared to control animals. As such, the instant specification provides numerous data indicating that the dosage disclosed in the prior art does reduce CV and thus does improve body weight uniformity.

Applicant next argues that that claims depending from new claim 30 recite that CV decreases by at least 0.5 or 0.8 as compared to controls, and since the prior art dosage is insufficient to improve body weight uniformity it necessarily cannot decrease CV.

This argument is not persuasive for the reasons above concerning body weight uniformity. Inspection of Table 1 yields multiple trials wherein at a dosage of 0.5g/kg, CV decreased by greater than 0.8 (specifically trial 2, 7.281 vs. 3.353, trial 3, 16.766 vs. 10.921, trial 5, 12.163 vs. 2.825, and trial 5, 12.163 vs. 10.942, wherein the first number is the control value and the second number is the experimental value). Based upon this data, applicant's argument is not persuasive.

Applicant's last argument is that body weight uniformity is not like light or dark hair color and thus observation of the intended result is not inherent upon practicing the invention.

This argument is not persuasive for the reasons of record. How can antibodies be administered to subject without observing and monitoring the subject? Additionally, observation or the recognition of an inherent property does not impart patentability.

Applicant's arguments filed May 13, 2008 have been fully considered but they are not persuasive. Applicant repeats arguments already of record that there is no statistical significance at a dosage of 0.5 g/kg, has provided another declaration by inventor Minder Yang under 37 CFR 1.132 to this effect, and has argued that the examiner has misinterpreted the data in a way that one skilled in the art would not accept.

This argument is not persuasive. As has been previously stated, no dosages are recited in the claims indicated as rejected, nor do they recite statistical significance. Thus, applicant is arguing limitations not claimed. Note further that the issued claims of the '930 patent also do not recite, and are thus not limited, to any specific dosage.

Applicant has also argued that claims 27 and 40 have been amended to recite a positive measuring step that is not taught in the prior art.

This argument is not persuasive in that to measure body weight uniformity, a person of ordinary skill in the art must weigh the animals. The '930 patent discloses weighing the animals at a time subsequent to administration (see particularly lines 37-38 of column 4). As such, the '930 patent discloses the positively recited method steps, namely administering and weighing.

The rejection is maintained.

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4. Claims 1, 5-10, 12, 25, 27, and 30-40 stand rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 6,383,485, (see entire document) for the reasons of record.

The office action mailed January 24, 2007 states:

The '485 patent teaches methods of administering anti-phospholipase A₂ (anti-PLA₂) antibodies to animals to enhance animal growth and feed efficiency. This patent teaches that PLA₂ cleaves the covalent bond between arachidonic acid and membrane phospholipids, thus releasing arachadonic acid to serve as a prostaglandin/leukotriene precursor (see particularly lines 46-51 of column 1). Note that anti-PLA₂ antibodies are disclosed as inhibiting the activity of PLA₂ which thus effectively limit the bioavailability of arachidonic acid (see particularly lines 26-53 of column 2). Animals to be administered anti-PLA₂ antibodies comprise chickens, ducks, turkeys, quail, geese, cows, sheep, pigs, and goats (see particularly lines 10-15 of column 3). The anti-PLA₂ antibodies are administered by a variety of routes, comprising subcutaneously, intraperitoneal, intramuscular, intravenous, and oral, with the oral route being preferred (see particularly lines 52-63 of column 3). The '485 patent further teaches that anti-PLA₂ antibodies can be obtained from the yolk of immunized chickens, and that egg preparations comprising the specific antibody are to be given as a supplement to the animal's diet (see particularly from line 64 of column 3 to line 22 of column 4).

It is noted that the preamble of the instant claims recite "improving body weight uniformity" and "increasing carcass yield" and that these particular phrases are not found within the text of the '485 patent. However, the process steps of the instant claims comprise administering an agent, such as an anti-PLA₂ antibody, to an animal. These process steps are taught by the '485 patent as discussed above. As such it appears that improved body weight uniformity and increased carcass yield are inherent benefits that accrue to an animal upon performance of the methods of administering anti-PLA₂ antibodies disclosed in the '485 patent. Applicant is reminded "[T]he discovery of a previously unappreciated property of a prior art composition (method), or of a scientific explanation for the prior art's functioning, does not render the old composition (method) patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Further, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also Toro Co. v. Deere & Co., 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."). Given that the same agent is administered to the same patient population, the methods of the '485 patent anticipate the claimed invention.

And the office action mailed July 11, 2007 states:

Applicant's arguments filed April 24, 2007 have been fully considered but they are not persuasive. Applicant's argument is the same as that discussed above concerning the anticipation of the instant invention by the '930 patent. This issue is adequately addressed above and will not be addressed further.

And the office action mailed December 19, 2007 states:

Applicant's arguments filed October 10, 2007 have been fully considered but they are not persuasive. Applicant's arguments are the same as those presented above in conjunction with the '930 patent. These arguments have been addressed above and will not be addressed further.

Applicant's arguments filed May 13, 2008 have been fully considered but they are not persuasive. Applicant's arguments are the same as those presented above in conjunction with the '930 patent. These arguments have been addressed above and will not be addressed further.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 29 stands rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,213,930 (of record on the 4/29/04 IDS, see entire document) in view of Pimentel (Feedstuffs, 1999, 71:12-14, 18-19) for the reasons of record.

The office action mailed December 19, 2007 states:

The disclosure of the '930 patent has been discussed above, and differs from the instant claimed invention in that while a dosage of 0.5g/kg is disclosed, dosages in the range of 0.6-2.4g/kg are not disclosed.

Pimentel discloses that eggs, and consequently the antibodies present in dried egg powder, are generally recognized as safe (GRAS), and as such can be used as feed additives (see entire document, particularly the last column of page 18). Pimentel also summarizes multiple studies conducted by others wherein yolk antibodies were administered at various concentrations in a variety of settings to improve health, body weight gain and feed conversion efficiency.

As such, it would have been obvious to a person of ordinary skill in the art to perform the administration methods disclosed in the '930 patent using a dosage of more than 0.5g/kg at the time the instant invention was performed. Motivation to do so comes from the fact that it is routine for artisans to optimize dosages when performing in vivo methods. Indeed, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955) and MPEP § 2144. As

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discussed earlier in this office action, the dosages disclosed in the prior art achieve improvements in body weight uniformity, and as such changing the administered dosage amounts to routine, obvious optimization. The person of ordinary skill in the art would also be motivated to and have a reasonable expectation of success in administering more antibody since as disclosed by Pimentel, egg antibodies are considered GRAS and thus administering additional antibody would not reasonably be expected to be detrimental to the patient.

Applicant's arguments filed May 13, 2008 have been fully considered but they are not persuasive. Applicant argues that because the dosage range disclosed in the prior art is insufficient to improve body weight uniformity, there is no motivation to combine and no expectation of success in combining the cited references.

The argument concerning the insufficiency of the '930 patent has been discussed previously in this office action and will not be elaborated further.

The rejection is maintained.

7. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent anticipated by US Patent 6,383,485, (of record, see entire document) in view of Pimentel (Feedstuffs, 1999, 71:12-14, 18-19) for the reasons of record.

The office action mailed December 19, 2007 states:

The disclosure of the '485 patent has been discussed above, and differs from the instant claimed invention in that while a dosage of 0.5g/kg is disclosed, dosages in the range of 0.6-2.4g/kg are not disclosed.

Pimentel discloses that eggs, and consequently the antibodies present in dried egg powder, are generally recognized as safe (GRAS), and as such can be used as feed additives (see entire document, particularly the last column of page 18). Pimentel also summarizes multiple studies conducted by others wherein yolk antibodies were administered at various concentrations in a variety of settings to improve health, body weight gain and feed conversion efficiency.

As such, it would have been obvious to a person of ordinary skill in the art to perform the administration methods disclosed in the '485 patent using a dosage of more than 0.5g/kg at the time the instant invention was performed. Motivation to do so comes from the fact that it is routine for artisans to optimize dosages when performing in vivo methods. Indeed, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955) and MPEP § 2144. As discussed earlier in this office action, the dosages disclosed in the prior art achieve improvements in body weight uniformity, and as such changing the administered dosage amounts to routine, obvious optimization. The person of ordinary skill in the art would also be motivated to and have a reasonable expectation of success in administering more antibody since as disclosed by Pimentel, egg antibodies are considered GRAS and thus administering additional antibody would not reasonably be expected to be detrimental to the patient.

Applicant's arguments filed May 13, 2008 have been fully considered but they are not persuasive. Applicant argues that because the dosage range disclosed in the prior

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art is insufficient to improve body weight uniformity, there is no motivation to combine and no expectation of success in combining the cited references.

The argument concerning the insufficiency of the '485 patent has been discussed previously in this office action and will not be elaborated further.

The rejection is maintained.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 5-10, 12, 25, 27 and 30-40 stand rejected under on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,213,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant invention for the reasons of record.

The office action mailed April 24, 2007 states:

Specifically, patented claim 1 recites “administering to said animal an agent that reduces the bioavailability in the animal of a prostaglandin or leukotrienes lipid precursor, wherein the agent comprises an antibody”. The independent claims in the instant application are not limited to administering antibodies,

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and as such the patented method claims anticipate the instant invention. Note that dependent patented claims recite anti-PLA₂ antibodies, that mammals such as cows and avians such as chickens are subjects for antibody administration, and that the antibodies can be administered by various injection routes or orally mixed with food, such as an egg preparation that comprises antibodies.

It is noted that the patented claims recite that the antibodies are administered to "enhance growth and feeding behavior" while the instant methods are recited as "improving body weight uniformity" and "increasing carcass yield". However, as discussed above, the antibodies administered in the patented claims anticipate the instant recited genus of administered agents and the populations to whom the agents are administered are not distinctly different. Therefore, "improved body weight" and "increased carcass yield" are inherent properties that arise when the patented method is performed in an animal.

Applicant is reminded "[T]he discovery of a previously unappreciated property of a prior art composition (method), or of a scientific explanation for the prior art's functioning, does not render the old composition (method) patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

And the office action mailed July 11, 2007 states:

Applicant's arguments filed April 24, 2007 have been fully considered but they are not persuasive. Applicant's argument is that performing the methods claimed in the '930 patent does not yield improved body weight uniformity, and argues that that the declaration under 37 CFR 1.132 of coinventor Mingder Yang supports this argument.

This argument is not persuasive for the reasons discussed above in conjunction with the anticipation of the instant invention by the '930 patent.

And the office action mailed December 19, 2007 states:

Applicant's arguments filed October 10, 2007 have been fully considered but they are not persuasive. Applicant's arguments are the same as those presented above in conjunction with the anticipation rejections. These arguments have been addressed above and will not be addressed further.

Applicant's arguments filed May 13, 2008 have been fully considered but they are not persuasive. Applicant argues that the present claims are patentably distinct from the issued claims in that "the dosage claimed differs from the dosage disclosed in the cited patents. Accordingly, withdrawal of the non-statutory obviousness-type double patenting rejections is respectfully requested."

This argument is not persuasive. Note that neither the patented claims nor the claims included in this rejection recite any dosage. Thus applicant is arguing patentability upon unclaimed limitations.

The rejection is maintained.

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10. Claims 1, 5-10, 12, 25, 27 and 30-40 are rejected under on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,383,485. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant invention for the reasons of record.

The office action mailed April 24, 2007 states:

Specifically, patented claim 1 recites "administering to said animal an agent that reduces the bioavailability in the animal of a prostaglandin or leukotrienes lipid precursor, wherein the agent comprises an antibody". The independent claims in the instant application are not limited to administering antibodies, and as such the patented method claims anticipate the instant invention. Note that dependent patented claims recite anti-PLA₂ antibodies, that mammals such as cows and avians such as chickens are subjects for antibody administration, and that the antibodies can be administered by various injection routes or orally mixed with food, such as an egg preparation that comprises antibodies. It is noted that the patented claims recite that the antibodies are administered to "reduce gastrointestinal inflammation" while the instant methods are recited as "improving body weight uniformity" and "increasing carcass yield". However, as discussed above, the antibodies administered in the patented claims anticipate the instant recited genus of administered agents and the populations to whom the agents are administered are not distinctly different. Therefore, "improved body weight" and "increased carcass yield" are inherent properties that arise when the patented method is performed in an animal.

Applicant is reminded "[T]he discovery of a previously unappreciated property of a prior art composition (method), or of a scientific explanation for the prior art's functioning, does not render the old composition (method) patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

And the office action mailed July 11, 2007 states:

Applicant's arguments filed April 24, 2007 have been fully considered but they are not persuasive. Applicant's argument is that performing the methods claimed in the '930 patent does not yield improved body weight uniformity, and argues that that the declaration under 37 CFR 1.132 of coinventor Mingder Yang supports this argument.

This argument is not persuasive for the reasons discussed above in conjunction with the anticipation of the instant invention by the '930 patent.

The rejection is maintained.

And the office action mailed December 19, 2007 states:

Applicant's arguments filed October 10, 2007 have been fully considered but they are not persuasive. Applicant's arguments are the same as those presented above in conjunction with the anticipation rejections. These arguments have been addressed above and will not be addressed further.

Applicant's arguments filed May 13, 2008 have been fully considered but they are not persuasive. Applicant argues that the present claims are patentably distinct from the issued claims in that "the dosage claimed differs from the dosage disclosed in the

cited patents. Accordingly, withdrawal of the non-statutory obviousness-type double patenting rejections is respectfully requested."

This argument is not persuasive. Note that neither the patented claims nor the claims included in this rejection recite any dosage. Thus applicant is arguing patentability upon unclaimed limitations.

The rejection is maintained.

11. Claim 29 stands rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,213,930 in view of in view of Pimentel (Feedstuffs, 1999, 71:12-14, 18-19) for the reasons of record.

The office action mailed December 19, 2007 states:

The claims of the '930 patent have been discussed above

Pimentel discloses that eggs, and consequently the antibodies present in dried egg powder, are generally recognized as safe (GRAS), and as such can be used as feed additives (see entire document, particularly the last column of page 18). Pimentel also summarizes multiple studies conducted by others wherein yolk antibodies were administered at various concentrations in a variety of settings to improve health, body weight gain and feed conversion efficiency.

As such, it would have been obvious to a person of ordinary skill in the art to perform the administration methods recited in the '930 patent using a dosage within the range recited in the instant claim at time the instant invention was performed. Motivation to do so comes from the fact that it is routine for artisans to optimize dosages when performing in vivo methods. Indeed, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955) and MPEP § 2144. As discussed earlier in this office action, the dosages disclosed in the prior art achieve improvements in body weight uniformity, and as such changing the administered dosage amounts to routine, obvious optimization. The person of ordinary skill in the art would also be motivated to and have a reasonable expectation of success in administering more antibody since as disclosed by Pimentel, egg antibodies are considered GRAS and thus administering additional antibody would not reasonably be expected to be detrimental to the patient.

Applicant's arguments filed May 13, 2008 have been fully considered but they are not persuasive. Applicant repeats the arguments discussed previously for why the instant claim was not obvious in view of the prior art references.

This argument is not persuasive for the reasons discussed earlier in this office action. The rejection is maintained.

12. Claim 29 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,383,485 in view of in view of Pimentel (Feedstuffs, 1999, 71:12-14, 18-19) for the reasons of record.

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The office action mailed December 19, 2007 states:

The claims of the '485 patent have been discussed above

Pimentel discloses that eggs, and consequently the antibodies present in dried egg powder, are generally recognized as safe (GRAS), and as such can be used as feed additives (see entire document, particularly the last column of page 18). Pimentel also summarizes multiple studies conducted by others wherein yolk antibodies were administered at various concentrations in a variety of settings to improve health, body weight gain and feed conversion efficiency.

As such, it would have been obvious to a person of ordinary skill in the art to perform the administration methods recited in the '485 patent using a dosage within the range recited in the instant claim at time the instant invention was performed. Motivation to do so comes from the fact that it is routine for artisans to optimize dosages when performing in vivo methods. Indeed, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955) and MPEP § 2144. As discussed earlier in this office action, the dosages disclosed in the prior art achieve improvements in body weight uniformity, and as such changing the administered dosage amounts to routine, obvious optimization. The person of ordinary skill in the art would also be motivated to and have a reasonable expectation of success in administering more antibody since as disclosed by Pimentel, egg antibodies are considered GRAS and thus administering additional antibody would not reasonably be expected to be detrimental to the patient.

Applicant's arguments filed May 13, 2008 have been fully considered but they are not persuasive. Applicant repeats the arguments discussed previously for why the instant claim was not obvious in view of the prior art references.

This argument is not persuasive for the reasons discussed earlier in this office action. The rejection is maintained.

13. No claims are allowable.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is (571)272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Primary Examiner
Art Unit 1644

/Michael Szperka/
Primary Examiner, Art Unit 1644